510k summary

K120865

Special 510(k) Notification

JUL 19 2012

510(k): RScribe Electrocardiograph Device Summary

Submitter: **Date: July 18, 2012**

Charles Morreale, Director of Regulatory Affairs and Quality Assurance
Mortara Instrument, Inc.
7865 N. 86th Street
Milwaukee, WI 53224
FAX: (414) 354-4760
Phone: (414) 354-1600
Contact: Charles Morreale (see above)

Trade Name: RScribe Electrocardiograph
Common Name: Electrocardiograph
Classification Name: Electrocardiograph
(Per 21 CFR 870.2340)

Legally marketed devices to which S.E. is claimed:

The Mortara Instruments RScribe Electrocardiograph is substantially equivalent to the legally marketed devices presently in distribution:

- Mortara Instrument ELI PC Electrocardiograph (K093339).
- Mortara Instrument ELI 230 Electrocardiograph (K100127)

Description:

The proposed Mortara Instrument RScribe is an electrocardiograph that combines proprietary hardware and an off-the-shelf personal computer. The RScribe is intended to be used with the Mortara Wireless Acquisition Module (WAM) or Mortara Acquisition Module (AM12) patient cables. The RScribe acquires ECG waveforms from the WAM or the AM12 patient cable.

The system is based on the following components:

- The RScribe is compatible with proprietary detachable patient applied lead sets. The RScribe acquires ECG waveforms from the Mortara Wireless Acquisition Module (WAM) or Mortara Acquisition Module (AM12) patient cables. The received ECG data will be first analyzed to determine the quality of the ECG then the record will be analyzed using the latest VERITAS™ Resting Interpretation criteria (adults / pediatric, K082946) used in other Mortara Electrocardiographs. The analyzed ECG will be displayed on the PC screen and will include measurements performed by the interpretation algorithm and the text of the automatic analysis. The user will have the possibility to edit the patient demographic data and, also the interpretation text.

- RScribe allows the user to schedule new exams and viewing of the existing schedule. The system controls user access and authentication, submits demographic and visit information to the repository. It also allows the user to view scheduled modality procedures, select the appropriate exams and enter patient demographics and download modality worklist when necessary.

- After the exams are saved, the reports will be generated (Report Generator) upon request of the modality application. The request includes the template file and data necessary to generate the report. User is also able to print the report and/or export it to a pdf file. The Report Viewer will provide the possibility to open saved reports and read the data directly from the report file. It allows the user to print to a selected windows printer, Mortara Z200+ printer, the ability to zoom the previewed final report, enable/disable the display and print of grid and navigation of the report pages.

The received ECG data will be first analyzed to determined the quality of the ECG then the record will be analyzed using the Mortara Resting Interpretation (adults and pediatric). The analyzed ECG will be displayed on the PC screen and it will include measurements performed by the interpretation algorithm and the text of the automatic analysis. The user will have the possibility to edit the patient demographic data and, in some versions of the product, also the interpretation text.

The user will be able to store the record on the local hard disk or on a networked server. In addition, printouts will be possible as well as file export in several formats (DICOM, UNIPRO32, XML, FDA-XML, etc).

Additional to the above mentioned features, the RScribe will be capable of being interfaced with Hospital Information System (or similar) in order to receive patient demographics.

The user interface of the RScribe will also be customizable in order to better fit the customer workflow. RScribe implements the latest VERITAS™ Resting Interpretation criteria (adult/pediatric) (ELI 350 K082946).

Intended Use:

The RScribe Electrocardiograph is a multi-channel electrocardiograph product used for acquiring, analyzing, displaying and printing resting ECG's. The RScribe is a 12-channel diagnostic electrocardiograph intended for recording and printing ECG's of adult and pediatric patients. The acquired ECG will be displayed for quality check purpose, analyzed using the Mortara VERITAS resting interpretation, optionally printed, stored and/or transmitted to a ECG Management System or Hospital Information System. The device is not intended to be used as a vital signs physiological monitor.

It is a system comprised of a Mortara ECG amplifier (Wireless Acquisition Module [WAM] or AM12 Patient Cable) and an off-the-shelf personal computer with Mortara software application that allows clinicians to collect ECGs on patients during routine visits. The patient populations for which the device will be used may be healthy or diseased of any age. ECG's are taken with the patient in the supine position. The RScribe is intended to be used by a licensed health care practitioner in a hospital, medical clinic and offices of any size, including Clinical Research Organizations.

Indications for Use:

The proposed Mortara RScribe Electrocardiograph is a non-invasive prescription device.

- The device is indicated for use to acquire, analyze, display, transmit and print electrocardiograms.
- The device is indicated for use to provide interpretation of the data for consideration by a physician.
- The device is indicated for use in a clinical setting, by a physician or by trained personnel who are acting on the orders of a licensed physician. It is not intended as a sole means of diagnosis.
- The interpretations of ECG offered by the device are only significant when used in conjunction with a physician over-read as well as consideration of all other relevant patient data.
- The device is indicated for use on adult and pediatric populations.
- The device is not intended to be used as a vital signs physiological monitor.
- The device is not designed for out of hospital transport.
- The device is not designed for use in highly invasive environments, such as an operating theatre.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JUL 19 2012

Mortara, Inc.
c/o Mr. Charles Morreale
Director of Regulatory Affairs and Quality Assurance
7865 North 86th Street
Milwaukee, WI 53224

Re: K120865
Trade/Device Name: RScribe Electrocardiograph
Regulation Number: 21 CFR 870.2340
Regulation Name: Electrocardiograph
Regulatory Class: Class II (two)
Product Code: DPS
Dated: June 22, 2012
Received: June 25, 2012

Dear Mr. Morreale:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K120865

Device Name: **Mortara RScribe Electrocardiograph**

Indications for Use:

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Prescription Use ___X____ (21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K120865

Concurrence of CDRH, Office of Device Evaluation (ODE)